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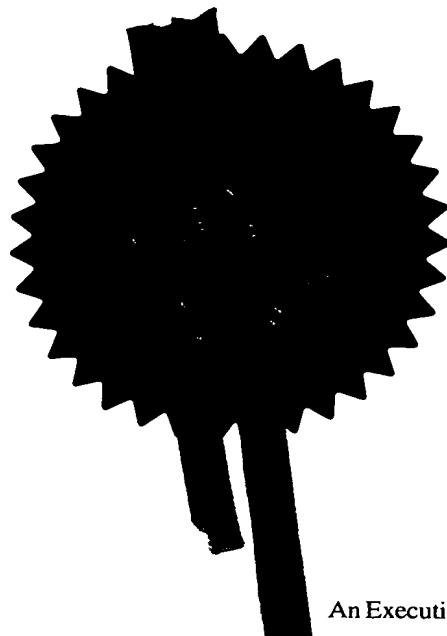
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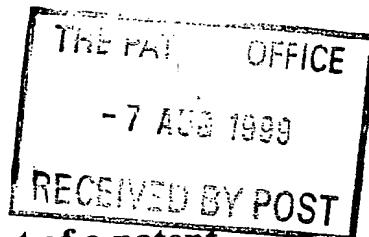
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Patents ADP number (if you know it)

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004735 87 002

4 Title of the invention

VALVE

5 Name of your agent (if you know one)

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Request for preliminary examination and search (Patent Form 9/77)

Request for substantive examination (Patent Form 10/77)

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11. I request the grant of a patent on the basis of this application

 
Signature Christopher Gerard Pike
AGENT FOR THE APPLICANTS

6 August 1999

12. Name and daytime telephone number of person to contact in the United Kingdom

Dr. Christopher G. Pike
01628 471869

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Valve

5

Field of invention

10 This invention relates to a valve for an aerosol container with the aid of which a quantity of the contents thereof can be dispensed. The invention has particular application to the dispensing of metered doses of medicaments, though it is applicable to the dispensing of aerosols generally.

15 **Background to the invention**

Containers for aerosol formulations commonly comprise a vial body coupled to a valve. The valve comprises a valve stem through which the formulation is dispensed. Generally the valve includes a rubber valve seal intended to allow 20 reciprocal movement of the valve stem while preventing leakage of propellant from the container.

It has been found that in some conventional devices the valve stem tends to drag during the actuation cycle with the result that the user perceives a 25 'notchiness' as the valve stem is depressed and released. This may be partly caused by the drug sedimenting or precipitating out of the drug-propellant suspension or solution formulation and depositing on the internal valve components, the presence of drug on the sliding interface creating increased friction during operation.

30 Prior art seals generally comprise a rubber ring formed by stamping out of a ring shape from a sheet of rubber material. The ring aperture, thus, inevitably has

square-cut edges which present a relatively high area of contact between the seal and the stem. Furthermore, when the valve stem is moved in such square-cut seals the seal deforms in such a way that the surface area, and hence the frictional contact area, between the seal and stem increases.

5

The Applicants have now found that the above described problem of notchiness may be ameliorated without compromising sealing performance if the valve seal has a wiper component in addition to a sealing portion. The wiper acts on the valve stem to prevent the deposit and accumulation of drug particles and 10 propellant at the point of contact between the sealing portion and the valve stem. The 'notchiness' that usually increases with repeated actuations of the aerosol container is therefore reduced.

Summary of the invention

15

According to one aspect of the present invention there is provided a valve for an aerosol container, the valve comprising a valve body; within said valve body, a sealing ring including a sealing portion; and receivable by said sealing portion, a valve stem having a dispensing passage, the valve stem being slidably movable within the sealing ring from a valve-closed position to a valve-open position in 20 which the interior of the valve body is in communication with the dispensing passage, wherein the sealing ring further includes a wiper to wipe the valve stem.

25

The wiper is typically longer and thinner than the sealing portion of the sealing ring.

30

Preferably the valve body has a metering chamber, a sampling chamber and therebetween is provided a second sealing ring, including a sealing portion, within which the stem is slidably movable, the valve stem having a transfer passage such that in the valve-closed position the dispensing passage is isolated from the metering chamber and the metering chamber is in

communication with the sampling chamber via said transfer passage, and in the valve-open position the dispensing passage is in communication with the metering chamber and the transfer passage is isolated from the metering chamber, wherein the second sealing ring further includes a wiper to wipe the valve stem.

5

The wiper is typically longer and thinner than the sealing portion of the second sealing ring.

10 Preferably the wiper is an integral part of the sealing ring or second sealing ring.

Preferably the wiper of the sealing ring or second sealing ring is in curved contact with the valve stem.

15 Preferably there is an enclosed space between the wiper, the sealing portion and the seal receiving part of the valve stem.

In one aspect the stem-receiving part of the sealing portion and wiper have rounded edges.

20

In one aspect the sealing portion and wiper are spaced by a layer of supporting rigid material.

25

Preferably the sealing ring and second sealing ring are formable by a moulding process. More preferably the moulding process is compression moulding or injection moulding.

Preferably the wiper is formed from a material selected from the group consisting of a thermoplastic elastomer and a mouldable rubber.

30

Preferably the sealing ring and/or second sealing ring is not movable relative to the valve body. More preferably the sealing ring and/or second sealing ring is held within a cavity in the valve body.

5 According to another aspect of the present invention there is provided an aerosol container comprising a valve as described hereinabove.

Preferably the aerosol container comprises a suspension of a medicament in a propellant. Preferably the propellant is liquefied HFA134a or HFA-227.

10 Preferably the medicament is selected from the group consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate, salts or solvates thereof and any combination thereof.

15 **Brief description of the drawings**

The invention will now be described further with reference to the accompanying drawings in which:

20 Figure 1 is a section through a prior art metering valve;

25 Figure 2a and 2b are close up sectional views of a seal-stem contact point in a valve according to the invention, showing two different arrangements and shapes of the sealing portion and wiper of the sealing ring or second sealing ring.

Detailed description of the drawings

30 A prior art metering valve is shown in Figure 1 and comprises a valve body 1 sealed in a ferrule 2 by means of crimping, the ferrule itself being set on the neck of a container (not shown) with interposition of a gasket 3 in a well-known

manner. The container is loadable with a suspension of medicament, such as salmeterol xinafoate in liquid propellant HFA134a.

5 The valve body 1 is formed at its lower part with a metering chamber 4, and its upper part with a sampling chamber 5 which also acts as a housing for a return spring 6. The words "upper" and "lower" are used for the container when it is in a use orientation with the neck of the container and valve at the lower end of the container which corresponds to the orientation of the valve as shown in Figure 1. Inside the valve body 1 is disposed a valve stem 7, a part 8 of which extends 10 outside the valve through lower stem seal 9 and ferrule 2. The stem part 8 is formed with an inner axial or longitudinal canal 10 opening at the outer end of the stem and in communication with a radial passage 11.

15 The upper portion of stem 7 has a diameter such that it can pass slidably through an opening in an upper stem seal 12 and will engage the periphery of that opening sufficiently to provide a seal. The stem seals 9 and 12 have an integral wiper blade to wipe the valve stem. Upper stem seal 12 is held in position against a step 13 formed in the valve body 1 between the said lower and upper parts by a sleeve 14 which defines the metering chamber 4 between 20 lower stem seal 9 and upper stem seal 12. The valve stem 7 has a passage 15 which, when the stem is in the inoperative position shown, provides a communication between the metering chamber 4 and sampling chamber 5, which itself communicates with the interior of the container via orifice 16 formed in the side of the valve body 1.

25 Valve stem 7 is biased downwardly to the inoperative position by return spring 6 and is provided with a shoulder 17 which abuts against lower stem seal 9. In the inoperative position as shown in Figure 1 shoulder 17 abuts against lower stem seal 9 and radial passage 11 opens below lower stem seal 9 so that the metering chamber 4 is isolated from canal 10 and suspension inside cannot 30 escape.

A ring 18 having a "U" shaped cross section extending in a radial direction is disposed around the valve body below orifice 16 so as to form a trough 19 around the valve body. As seen in Figure 1 the ring is formed as a separate component having an inner annular contacting rim of a diameter suitable to provide a friction fit over the upper part of valve body 1, the ring seating against step 13 below the orifice 16. However, the ring 18 may alternatively be formed as an integrally moulded part of valve body 1.

To use the device the container is first shaken to homogenise the suspension within the container. The user then depresses the valve stem 7 against the force of the spring 6. When the valve stem is depressed both ends of the passage 15 come to lie on the side of upper stem seal 12 remote from the metering chamber 4. Thus a dose is metered within the metering chamber. Continued depression of the valve stem will move the radial passage 11 into the metering chamber 4 while the upper stem seal 12 seals against the valve stem body. Thus, the metered dose can exit through the radial passage 11 and the outlet canal 10.

Releasing the valve stem causes it to return to the illustrated position under the force of the spring 6. The passage 15 then once again provides communication between the metering chamber 4 and sampling chamber 5. Accordingly, at this stage liquid passes under pressure from the container through orifice 16, through the passage 15 and thence into the metering chamber 4 to fill it.

Figure 1 illustrates a prior art valve with square cut valve seals while the current invention describes the use of a wiper seal to wipe the valve stem and consequently reduce the 'notchiness' during actuation of the inhaler device. The wiper and sealing portion of the sealing ring replace the square cut seals shown in Figure 1. The detail of the wiper and sealing portion of the sealing ring according to the invention are described below and illustrated in Figures 2a and 2b.

Figure 2a shows upright valve stem 108, which has a circular cross-section. A sealing ring 112 sealingly contacts the valve stem 108. The sealing ring 112 is comprised, at the stem receiving part, of a sealing portion 120 and a wiper 130. The wiper 130 is in curved contact with the valve stem 108 and is separated from the sealing portion 120 by an enclosed space 140. The wiper 130 wipes the valve stem 108 so that any particles are wiped away from the sealing portion 120 of the sealing ring 112. The wiper 130 is long and thin in comparison to the sealing portion 120 and the length of the wiper 130 may be varied for optimum performance

Figure 2b shows upright valve stem 208, which has a circular cross section. A sealing ring 212 sealingly contacts the valve stem 208. The sealing ring 212 is comprised, at the stem-receiving part, of a sealing portion 220 and a wiper 230. The wiper 230 and sealing portion 220 are separated at the stem receiving part by a small enclosed space 240 and are supported by a layer of rigid material 250. The wiper 230 wipes the valve stem 208 so that any particles are wiped away from the sealing portion 220 of the sealing ring 212. The wiper 230 is long and thin in comparison to the sealing portion 220 and the length of the wiper 230 may be varied for optimum performance. The supporting layer of rigid material 250 supports the sealing portion 220 and wiper 230 and reduces the deformation of the sealing portion 220 during movement of the valve stem 208. The supporting layer thereby reduces the surface contact area between the sealing portion 220 and the valve stem 208 and consequently further reduces the problem of 'notchiness'.

The aerosol container and valve of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders. Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or nedocromil; antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti- inflammatories, e.g.,

beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, 5 rofleponide, mometasone furoate or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro- α -[[[6-[2-(2-pyridinyl)ethoxy] hexyl]methyl] benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, 10 tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon. It will be clear to a person skilled in the art that, where appropriate, the 15 medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

20 Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an anti-inflammatory steroid such as a beclomethasone ester 25 (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

30 The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such

subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

Claims

1. Valve for an aerosol container, the valve comprising a valve body; within said valve body, a sealing ring including a sealing portion; and receivable by said sealing portion, a valve stem having a dispensing passage, the valve stem being slidably movable within the sealing ring from a valve-closed position to a valve-open position in which the interior of the valve body is in communication with the dispensing passage, wherein the sealing ring further includes a wiper to wipe the valve stem.

10

2. Valve according to claim 1, wherein the valve body has a metering chamber, a sampling chamber and therebetween is provided a second sealing ring, including a sealing portion, within which the stem is slidably movable, the valve stem having a transfer passage such that in the valve-closed position the dispensing passage is isolated from the metering chamber and the metering chamber is in communication with the sampling chamber via said transfer passage, and in the valve-open position the dispensing passage is in communication with the metering chamber and the transfer passage is isolated from the metering chamber, wherein the second sealing ring further includes a wiper to wipe the valve stem.

15

3. Valve according to either of claims 1 or 2 wherein the wiper is an integral part of the sealing ring or second sealing ring.

20

25

4. Valve according to any of claims 1 to 3 wherein the wiper of the sealing ring or second sealing ring is in curved contact with the valve stem.

30

5. Valve according to any of claims 1 to 4 wherein there is an enclosed space between the wiper, the sealing portion and the seal receiving part of the valve stem.

6. Valve according to any of claims 1 to 5 wherein the stem-receiving parts of the seal and wiper have rounded edges.
7. Valve according to any of claims 1 to 6 wherein the seal and wiper are spaced by a layer of supporting rigid material.
8. Valve according to any of claims 1 to 7, wherein the sealing ring is formable by a moulding process.
9. Valve according to claim 8 wherein the moulding process is compression moulding or injection moulding.
10. Valve according to any of claims 1 to 9, wherein the wiper is formed from a material selected from the group consisting of a thermoplastic elastomer and a mouldable rubber.
11. Valve according to any of claims 1 to 10, wherein the sealing ring and/or second sealing ring is not movable relative to the valve body.
12. Valve according to claim 11, wherein the sealing ring and/or second sealing ring is held within a cavity in the valve body.
13. Aerosol container comprising a valve according to any of claims 1 to 12.
14. Aerosol container according to claim 13 comprising a suspension of a medicament in a propellant.
15. Aerosol container according to claim 14, wherein, the propellant is liquefied HFA134a or HFA-227.

16. Aerosol container according to either of claims 14 or 15, wherein the medicament is selected from the group consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate, salts or solvates thereof and any combination thereof.

Abstract

There is provided a valve for an aerosol container. The valve comprises a valve body; within said valve body, a sealing ring including a sealing portion; and receivable by said sealing ring, a valve stem having a dispensing passage. The valve stem is slidably movable within the seal from a valve-closed position to a valve-open position in which the interior of the valve body is in communication with the dispensing passage. The sealing ring further includes a wiper to wipe the valve stem. Preferably, the valve is a metering valve.

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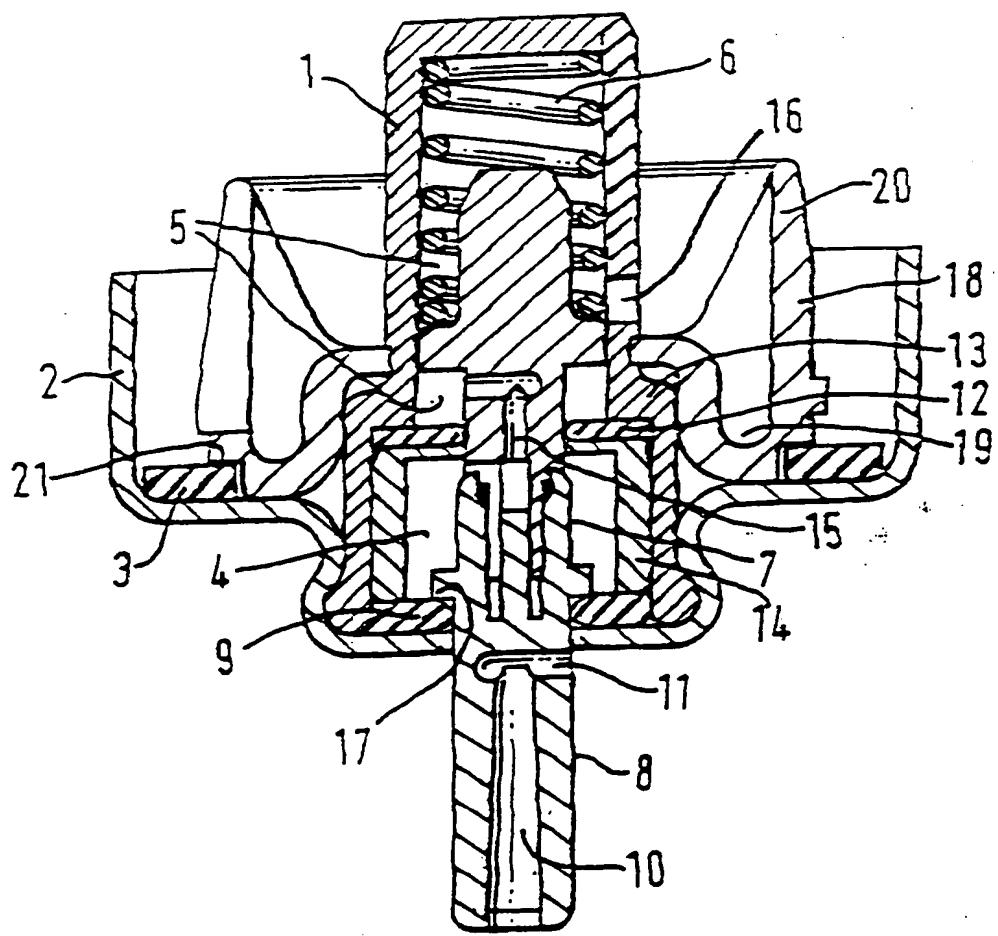


FIG. 1.

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Figure 2a

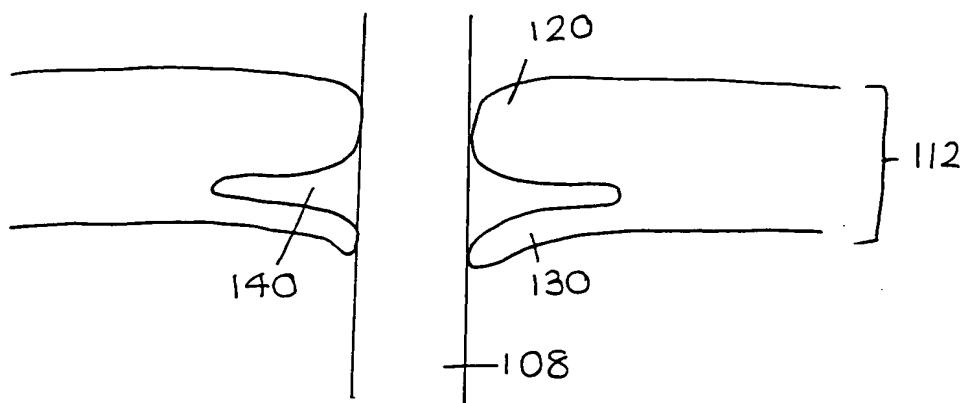
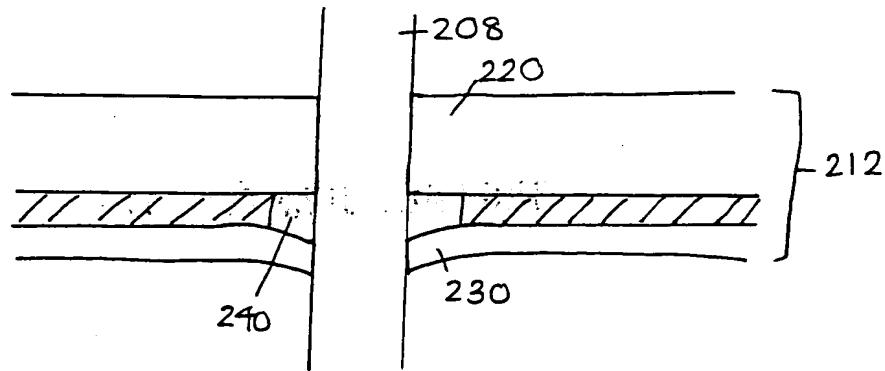


Figure 2b



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